PATIENT EDUCATION / SELF MANAGEMENT

WHAT YOU SHOULD KNOW: HEPATITIS C

Q: WHAT IS HEPATITIS C OR HEP C?

A: Hepatitis means inflammation (irritation) of the liver. The liver produces key nutrients, aids in digestion, and keeps waste products from building up in the body. There are no medications to heal the liver once it is damaged. The most common causes of liver irritation are viruses, drugs, and alcohol. Hep C is one of the viruses that can irritate the liver. Other common viruses are Hepatitis A and Hepatitis B.

Q: HOW DO YOU GET HEP C?

A: You get Hep C from dirty needles (tattoos, piercing with sharp things), snorting drugs with infected equipment, sharing works (drug equipment), unprotected sex (rarely), or from a blood transfusion received in the United States before 1992. Hep C is carried in the blood, but now blood is tested for Hep C prior to a transfusion.

Q: HOW DO YOU KNOW IF YOU HAVE HEP C?

A: Most people with Hep C look and feel fine. You can have Hep C for a long time and not know you have it. Usually Hep C is discovered by blood tests.

What tests are used for Hepatitis C screening?

HEPATITIS C ANTIBODY TEST (Hep C Ab) If your antibody test is "positive" then you have hepatitis C antibody in your blood.
What does that mean?
It means that sometime in your life you were infected with the Hepatitis C virus and you made proteins to fight the virus (antibodies). That's ALL we know. We do NOT know if the infection is still in your body (1 or 2 out of every 10 people infected with Hep C successfully fight the virus and it goes away). Once the antibody test is positive it generally stays positive for life even if you no longer have the Hepatitis C virus in your body.

HEPATITIS C VIRAL LOAD (Hep C Viral load, Hep C RNA, Heptimax). In order to tell if you still have Hepatitis C virus active in your body a "Viral Load" test is done. This test tells if Hep C virus is still present in your body- and if so, how much virus you have.
If you have active virus in your body you are considered to have **Chronic Hepatitis C** infection and you should be followed regularly by a doctor, physician's assistant , or nurse practitioner.

GENOTYPE The "variety" or "type" of Hepatitis C virus that you have. If there is evidence that you still have virus actively growing in your body, a genotype test is done to find out which type you have. There are 6 main varieties/types of Hepatitis C:

- **Genotype 2 and 3**
  - respond better to treatment- require only 24 weeks of medication
- **Genotype 1,4,5,6**
  - Genotype 1 is the most common in the United States
  - these genotypes do not respond as well to treatment and require 24-48 weeks of medication

Your genotype usually does not change unless you get an infection with another type of Hepatitis C so you only need to be checked once for genotype.

Q: HOW ARE PATIENTS WITH CHRONIC HEPATITIS C FOLLOWED?

A: Once we know you have active Hepatitis C virus in your body (called chronic Hepatitis C infection) we need to see if it is causing irritation or scarring in your liver. We do this by looking at blood tests:

LIVER IRRITATION: Blood tests called ALT, AST, GGT, T. Bilirubin
These tests measure different chemicals made by your liver. Increased amounts of these chemicals in your blood can mean that the Hepatitis C virus is irritating your liver. These tests can also be high because your liver is irritated for other reasons such as medications, alcohol, or other viruses.

LIVER SCARRING (CIRRHOSIS): Blood tests called platelet count, albumin, and INR
These tests tell us about how the liver is working and also give us clues about whether there is scar tissue forming in the liver because of damage from the Hepatitis C virus. If there is evidence of severe scarring in your liver (called cirrhosis) other testing is usually done. This includes a liver ultrasound which is done twice a year to look for evidence that liver cancer may be developing.

If you and your medical provider are deciding whether to consider treatment you may need a liver biopsy which requires that a sample of liver tissue be taken with a special biopsy needle. This test can tell more precisely the amount of scar tissue in your liver. Liver biopsy results are usually listed as Grade and Stage:

Grade of inflammation: this tells how much irritation the liver has at the time of the biopsy.

- Grade is usually scored from 0-4 with 0 being no activity and 3 or 4 considered severe activity.
- The amount of inflammation is important because it can lead to fibrosis.
- The inflammation score can improve, for example if you were drinking alcohol and then stopped.

Stage of fibrosis: this tells how much scar tissue is in the liver. Scarring usually will not improve, but it can slowly worsen.

- Stage of fibrosis: this tells how much scar tissue is in the liver. Scarring usually will not improve, but it can slowly worsen.
- Stage 0: no scarring (does not need treatment)
- Stage1: minimal scarring (too early to treat)
- Stage 2-3: moderate scarring
- Stage 4: severe scarring also called cirrhosis. When cirrhosis causes medical conditions such as bleeding, ascites (extra fluid in the abdomen), or confusion (known as encephalopathy) HCV cannot be treated

PATIENT EDUCATION / SELF MANAGEMENT

WHAT YOU SHOULD KNOW: HEPATITIS C (CONTINUED)

Q: HOW DO YOU FEEL WHEN YOU FIRST GET HEP C?
A: When they are first infected with Hepatitis C virus most people will have no signs or symptoms. Some people can have jaundice (turning yellow), fatigue (being tired), dark urine, abdominal pain, loss of appetite or nausea. These symptoms usually get better after a few days or weeks.

Q: HOW DO YOU FEEL WHEN YOU HAVE CHRONIC HEPATITIS C?
A: Many people with Chronic Hep C do not know that they have it until they have a blood test. A small percentage of people with chronic Hep C infection feel tired, have joint pain, stomach upset, night sweats, or feel sad.

Q. WILL HEPATITIS C SHORTEN MY LIFE?
- The majority (8 out of every 10) of people with Hepatitis C will live a normal life span and will die from other causes.
- In 1 or 2 out of ten people with chronic Hepatitis C infection, severe liver damage (cirrhosis) will develop over several years, and these people often die from complications of their Hepatitis C infection.

Q: CAN HEP C BE PREVENTED?
A: There is no vaccine or medicine to protect you from getting Hep C. Avoiding risk factors known to transmit the virus (such as sharing dirty needles, *etc*) is the best protection. Do not share razors, toothbrushes, piercing or tattoo equipment.
Hepatitis C is usually not transmitted through sex but safe sex practices should still be followed due to the risk of HIV and other STDs.

Q: IF I HAVE HEP C WHAT CAN I DO TO TAKE CARE OF MYSELF?
A: There are several things you can do including:
- Getting vaccinated against other types of hepatitis (A and B), pneumonia and the flu
- Do not drink alcohol or use street drugs - these worsen the damage to the liver
- Limit the use of medications, including acetaminophen (Tylenol®)and Motrin®-type medications (non-steroidal anti-inflammatories). Discuss use of all medications, including over-the-counter medications, vitamins, and herbs with your Primary Care Provider to be sure the medication is not damaging to your liver.

Q: IS CHRONIC HEPATITIS C TREATABLE?
A: There are medications that can be used to try to get rid of the virus. The treatment has many side effects, takes 6-12 months and is not always successful. Important things to know about Hepatitis C treatment:
- Not all people are eligible for treatment. If your liver is not showing damage from the virus, treatment is not needed at this time, and may never be needed. If your liver is showing severe damage (cirrhosis), treatment may not work or may be too dangerous.
- Because treatment takes several months and should not be interrupted once started, a patient in CDCR must have enough time remaining on his/her sentence to complete treatment before treatment will be considered:
  - Patients with genotype 2 or 3 (and not HIV infected) need at least 8 months left until parole
  - Patients with genotype 1, 4, 5,or 6 (and all HIV infected patients) need at least 16 months left until parole
  - Patients must be healthy enough to tolerate the treatment so patients with serious heart, lung, kidney, thyroid disease, seizure disorders or diabetes may not be eligible. Your case needs to be discussed with your Primary Care Provider to see if you qualify. Because the treatment (interferon) can cause depression, some patients with serious depression or other mental health issues may not be able to take the treatment.

Q: WHAT ARE THE MEDICATIONS USED IN HEPATITIS C TREATMENT?
A: Treatment is with pegylated interferon (weekly shots) and ribavirin (twice a day capsules). Patients with genotype 1 may receive treatment with boceprevir (capsules every 7 to 9 hours, taken with food) or telaprevir (tablets every 7 to 9 hours, taken with food) with pegylated interferon and ribavirin. Patients on treatment will have blood counts checked regularly so that adjustments to medications can be made if needed.

Q: SHOULD EVERYONE WITH HEPATITIS C BE TREATED?
A: No. The majority of people with chronic Hepatitis C will live a normal life span and die from other causes. However 1 or 2 out of ten people with Hepatitis C infection can develop severe liver damage and die from complications of their Hepatitis C. The question of who needs treatment is complicated and depends on many factors which are different in each person's case. You need to discuss your case with your Primary Care Provider.

Q: HOW SUCCESSFUL IS TREATMENT WITH HEPATITIS C MEDICATIONS?
A: Not everyone who completes treatment for Hep C is cured. The chance of a cure depends on:
Genotype: the chance of cure is higher in genotype 2 and 3, but with new treatment, the cure rate in genotype 1 is improving.
Age: persons under age 50 years are more likely to successfully clear their Hep C infection.
Race: persons of Asian descent are more likely, and persons of African descent are least likely, to respond well to Hep C treatment
Other Viruses: having HIV or Hep B decreases your chance of curing your Hep C with treatment.
Use of drugs/alcohol: if you use drugs or alcohol during treatment, you lower your chance of a cure. If you do clear your Hep C, you are not immune, and you are at risk of getting Hep C again if you start using injectable drugs or engage in other high risk activities (tattooing, *etc.*).
Obesity: Hep C treatment is less effective in those who are obese compared to those who are at a normal weight. Even losing 8-10 pounds can improve your chances for a cure.

Q: WHAT ARE THE RISKS OF HEPATITIS C TREATMENT?
A: The most common and troublesome side effects of:
- Interferon are fatigue, body aches, and mood changes, including depression. Low platelet count (cells that help blood clot) and low white blood cell count (white blood cells fight infection) are common and can be dangerous.
- Ribavirin is damage to red blood cells that may lead to low red blood cell levels (making you anemic). Ribavirin can also cause birth defects and it is very important to avoid pregnancy during treatment as well as for at least 6 months after therapy has been stopped.
- Boceprevir can also cause a low red and/or white blood cell count. It can cause a metallic taste in your mouth and can upset your stomach.
- Telaprevir can cause a rash and itching. If the rash becomes too severe, the medication needs to be stopped.

PATIENT EDUCATION / SELF MANAGEMENT

WHAT YOU SHOULD DO: HEPATITIS C

Q: IF I HAVE HEP C WHAT CAN I DO TO TAKE CARE OF MYSELF?
A: There are several things you can do including:

Getting **VACCINATED** against other types of hepatitis A and B. Usually this is done as a three shot series

#1 _____Date
#2 _____Date
#3 _____Date

Getting vaccinated to prevent some types of pneumonia

_____ Pneumovax Date

Getting vaccinated every year to prevent the flu
2012____2013_____2014_____2015_____2016_____

Vaccination is only part of hepatitis prevention that should include practicing safe sex and not sharing personal items that might have blood on them.

- Limit number of sex partners and use latex condoms every time.
- If you inject illegal drugs, stop shooting.
- If you cannot stop drug use, do not reuse or share needles or works.

Sexual activity and the use of needles for non-prescribed purposes is illegal within the California Department of Corrections and Rehabilitation and may lead to prosecution

YOUR TEST RESULTS:

HEP C ANTIBODY (Hep C Ab positive) that means that sometime in your life your body saw the virus and made proteins to fight the virus.

Your antibody: _____ _____Date

VIRAL LOAD (Hep C RNA) test. This tells IF the hepatitis C virus is still in your body- and if so, how much of it.

Your viral load: _____ _____Date

GENOTYPE of Hepatitis C you have. Your genotype usually does not change unless you get infected with another type of Hepatitis C.

Your genotype: _____ _____Date

LIVER IRRITATION: Blood test called ALT, AST, GGT, T. Bilirubin

Your tests for liver irritation:

_____ _____Date
_____ _____ Date

LIVER SCARRING (CIRRHOSIS): Blood tests called platelet count, albumin level, INR

Your tests for liver scarring:

_____ _____Date
_____ _____ Date

LIVER ULTRASOUND (US) test twice a year after cirrhosis is documented

Your last US: _____ _____Date

LIVER BIOPSY results (if considering treatment, exclude genotype 2&3):

Grade: _____ Stage: _____ _____Date

DO'S AND DON'TS

- DON'T DRINK ALCOHOL

- DON'T SHOOT OR SNORT DRUGS
- DON'T GET TATTOOS IN PRISON
- DON'T SHARE YOUR TOOTHBRUSH, RAZOR, OR OTHER PERSONAL ITEMS
- DO TRY TO LOSE WEIGHT IF YOU ARE OVERWEIGHT

- DO EAT A HEALTHY DIET
- DO DRINK PLENTY OF WATER
- DO GET PLENTY OF REST AND REGULAR EXERCISE

- DO QUIT SMOKING CIGARETTES
- DO ASK YOUR DOCTOR BEFORE YOU TAKE ANY PAIN MEDICINE
- YOU CAN TAKE ACETAMINOPHEN (TYLENOL) FOR PAIN OR OTHER ACETAMINOPHEN CONTAINING MEDICATIONS, BUT DON'T TAKE MORE THAN 2 GRAMS OF ACETAMINOPHEN OR 4 EXTRA STRENGTH PILLS A DAY
- DO NOT DONATE BLOOD, TISSUE, OR ORGANS

SEE YOUR DOCTOR FOR REGULAR CHECKUPS

PATIENT EDUCATION/SELF MANAGEMENT

Summary of "FDA Drug Safety Communication: Erythropoiesis-Stimulating Agents (ESAs): Procrit, Epogen and Aranesp" as it pertains to the use of Procrit® (erythropoietin) for our Hepatitis C patients who have become anemic from taking Ribavirin or Interferon.

Safety Announcement
FDA said in a safety announcement dated 02/16/2010, that it is requiring all Erythropoiesis-Stimulating Agents (ESAs) to be prescribed and used under a risk management program to ensure the safe use of these drugs. Procrit, which we may prescribe to our hepatitis C patients who have become anemic due to their use of Ribavirin or Interferon, is an ESA.

According to the safety announcement, studies have shown that ESAs can increase the risk of heart attack, heart failure, stroke, and blood clots in patients who use these drugs for conditions other than cancer.

This announcement was primarily focused on cancer patients and oncologists.

The announcement said that **healthcare professionals** who prescribe ESAs to patients who have anemia from causes other than cancer chemotherapy **are**:

- required to provide a copy of the *Medication Guide* to each patient or his/her representative when an ESA is dispensed
- not required to enroll in the ESA APPRISE Oncology program.

The announcement added that **patients** with chronic kidney failure, including those on dialysis and those not on dialysis, who are using ESAs **should**:

- Know that the use of ESAs can increase the risk for stroke, heart attack, heart failure, blood clots, and death.
- Read the *Medication Guide* to understand the benefits and risks of using an ESA.
- Get blood tests while using ESAs. The test results may help guide the course of therapy and lower the risks of using these drugs. Patients' healthcare professionals should make them aware of how often to have blood tests.
- Talk with their healthcare professional about any questions they have about the risks and benefits of using ESAs.

Additional Information
A separate FDA document saying that cases of severe anemia have been found in some patients being treated with Procrit stated:

> *Cases of pure red cell aplasia (PRCA) and of severe anemia, with or without other cytopenias, associated with neutralizing antibodies to erythropoietin have been reported in patients treated with PROCRIT®. This has been reported predominantly in patients with CRF receiving ESAs by subcutaneous administration. PRCA has also been reported in patients receiving ESAs while undergoing treatment for hepatitis C with interferon and ribavirin. Any patient who develops a sudden loss of response to PROCRIT®, accompanied by severe anemia and low reticulocyte count, should be evaluated for the etiology of loss of effect, including the presence of neutralizing antibodies to erythropoietin (see PRECAUTIONS: Lack or Loss of Response). If anti-erythropoietin antibody-associated anemia is suspected, withhold PROCRIT® and other ESAs. Contact CENTOCOR ORTHO BIOTECH at 1 888 2ASK OBI (1-888-227-5624) to perform assays for binding and neutralizing antibodies. PROCRIT® should be permanently discontinued in patients with antibody-mediated anemia. Patients should not be switched to other ESAs as antibodies may cross-react.*

The safety communication can be accessed through FDA's website at:
http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm200297.htm#SA

The Procrit Medication Guide is at:
http://www.fda.gov/downloads/Drugs/DrugSafety/UCM088988.pdf

This second document is at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/103234s5199lbl.pdf

PATIENT EDUCATION / SELF MANAGEMENT

MEDICATION GUIDE

PROCRIT® (PRO′–KRIT)
(epoetin alfa)

Read this Medication Guide before you start PROCRIT, each time you refill your prescription, and if you are told by your healthcare provider that there is new information about PROCRIT. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment. Talk with your healthcare provider regularly about the use of PROCRIT and ask if there is new information about PROCRIT.

What is the most important information I should know about PROCRIT?

Using PROCRIT can lead to death or other serious side effects.

Patients with cancer:

Your healthcare provider has received special training through the ESA APPRISE Oncology Program in order to prescribe PROCRIT. Before you can begin to receive PROCRIT, you must sign the ESA APPRISE Oncology Patient and Healthcare Professional (HCP) Acknowledgement Form to document that your healthcare provider discussed the risks of PROCRIT with you. When you sign this form, you are stating that you are aware of the risks associated with use of PROCRIT.

These risks include that your tumor may grow faster and you may die sooner when PROCRIT is used experimentally to try to raise your hemoglobin beyond the amount needed to avoid red blood cell transfusion or if you are not getting strong doses of chemotherapy. It is not known whether these risks exist when PROCRIT is given according to the FDA-approved directions for use.

You should discuss with your doctor:

- Why PROCRIT treatment is being prescribed.
- What are the chances you will get red blood cell transfusions if you do not take PROCRIT.
- What are the chances you will get red blood cell transfusions even if you take PROCRIT.
- How taking PROCRIT may affect the success of your cancer treatment.

If you decide to take PROCRIT, your healthcare provider should prescribe the smallest dose of PROCRIT to lower the chance of getting red blood cell transfusions.

- After you have finished your chemotherapy course, PROCRIT treatment should be stopped.

- PROCRIT does not improve the symptoms of anemia (lower than normal number of red blood cells), quality of life, fatigue, or well-being for patients with cancer.

All patients, including patients with cancer or chronic kidney failure:

- You may get serious heart problems such as heart attack, stroke, heart failure, and may die sooner if you are treated with PROCRIT to a hemoglobin level above 12 g/dL.

- You may get blood clots at any time while taking PROCRIT. If you are receiving PROCRIT and you are going to have surgery, talk to your healthcare provider about whether or not you need to take a blood thinner to lessen the chance of blood clots during or following surgery. Clots can form in blood vessels (veins), especially in your leg (deep venous thrombosis or DVT). Pieces of a blood clot may travel to the lungs and block the blood circulation in the lungs (pulmonary embolus).

PATIENT EDUCATION / SELF MANAGEMENT

Call your healthcare provider or get medical help right away if you have any of these symptoms of blood clots:

- Chest pain
- Trouble breathing or shortness of breath
- Pain in your legs, with or without swelling
- A cool or pale arm or leg
- Sudden confusion, trouble speaking, or trouble understanding others' speech
- Sudden numbness or weakness in your face, arm, or leg, especially on one side of your body
- Sudden trouble seeing
- Sudden trouble walking, dizziness, loss of balance or coordination
- Loss of consciousness (fainting)
- Hemodialysis vascular access stops working. If you are a patient with chronic kidney failure and have a hemodialysis vascular access, blood clots may form in this access.

Also see **"What are the possible side effects of PROCRIT?"** below.

What is PROCRIT?

PROCRIT is a man-made form of the protein human erythropoietin that is given to patients to lessen the need for red blood cell transfusions. PROCRIT stimulates your bone marrow to make more red blood cells. Having more red blood cells raises your hemoglobin level. If your hemoglobin level stays too high or if your hemoglobin goes up too quickly, this may lead to serious health problems which may result in death. These serious health problems may happen even if you take PROCRIT and do not have an increase in your hemoglobin level.

PROCRIT may be used to treat a lower than normal number of red blood cells (anemia) if it is caused by:

- Chronic kidney failure (you may or may not be on dialysis)
- Chemotherapy that is used for at least two months to treat some types of cancer
- A medicine called zidovudine (AZT) used to treat HIV infection

PROCRIT may also be used if you are scheduled for certain surgeries with a lot of blood loss to reduce the chance you will need red blood cell transfusions.

PROCRIT should not be used for treatment of anemia:

- In place of emergency treatment (red blood cell transfusions)
- If you have cancer and you are not receiving chemotherapy that may cause anemia
- If your cancer has a high chance of being cured

PROCRIT should not be used if you are scheduled for certain surgeries and you are able and willing to donate blood prior to surgery.

Who should not take PROCRIT?

Do not take PROCRIT if you:

- Have cancer and have not been counseled by your healthcare provider regarding the risks of PROCRIT and signed the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgement Form before you begin to receive PROCRIT.
- Have high blood pressure that is not controlled (uncontrolled hypertension).
- Have been told by your healthcare provider that you have or have ever had a type of anemia called Pure Red Cell Aplasia (PRCA) that starts after treatment with PROCRIT or other erythropoietin medicines.

- Have allergies to any of the ingredients in PROCRIT. See the end of this Medication Guide for a complete list of ingredients in PROCRIT.

Do not give PROCRIT from multidose vials to premature babies.

What should I tell my healthcare provider before taking PROCRIT?

PROCRIT may not be right for you. **Tell your healthcare provider about all your health conditions**, including if you:

- Have heart disease.
- Have high blood pressure.
- Have had a seizure (convulsion) or stroke.
- Are pregnant or planning to become pregnant. It is not known if PROCRIT may harm your unborn baby. Talk with your healthcare provider about possible pregnancy and birth control choices that are right for you.
- Are breast-feeding or planning to breast-feed. It is not known if PROCRIT passes into breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines with you and show it to your healthcare provider when you get a new medicine.

How should I take PROCRIT?

Patients with cancer:

Before you begin to receive PROCRIT, your healthcare provider will:

- Ask you to review this PROCRIT Medication Guide
- Explain the risks of PROCRIT and answer all your questions about PROCRIT
- Have you sign the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgement Form

All patients:

- Continue to follow your healthcare provider's instructions for diet, dialysis, and medicines, including medicines for high blood pressure, while taking PROCRIT.
- Have your blood pressure checked as instructed by your healthcare provider.
- If you or your caregiver has been trained to give PROCRIT shots (injections) at home:
  - Be sure that you read, understand, and follow the "Patient Instructions for Use" that come with PROCRIT.
  - Take PROCRIT exactly as your healthcare provider tells you to. Do not change the dose of PROCRIT unless told to do so by your healthcare provider.
  - Your healthcare provider will show you how much PROCRIT to use, how to inject it, how often it should be injected, and how to safely throw away the used vial, syringes, and needles.
  - If you miss a dose of PROCRIT, call your healthcare provider right away and ask what to do.
  - If you take more than the prescribed amount of PROCRIT, call your healthcare provider right away.

What are the possible side effects of PROCRIT?

PROCRIT may cause serious side effects. See **"What is the most important information I should know about PROCRIT?"**

Other side effects of PROCRIT, which may also be serious, include:

- **High blood pressure in patients with chronic kidney failure.** Your blood pressure may go up or be difficult to control with blood pressure medicine while taking PROCRIT. This can happen even if you have never had high blood pressure before. Your healthcare provider should check your blood pressure often. If your blood pressure does go up, your healthcare provider may prescribe new or more blood pressure medicine.
- **Seizures.** If you have any seizures while taking PROCRIT, get medical help right away and tell your healthcare provider.
- **Antibodies to PROCRIT.** Your body may make antibodies to PROCRIT. These antibodies can block or lessen your body's ability to make red blood cells and cause you to have severe anemia. Call your healthcare provider if you have unusual tiredness, lack of energy, dizziness, or fainting. You may need to stop taking PROCRIT.
- **Serious allergic reactions.** Serious allergic reactions can cause a rash over your whole body, shortness of breath, wheezing, dizziness and fainting because of a drop in blood pressure, swelling around your mouth or eyes, fast pulse, or sweating. If you have a serious allergic reaction, stop using PROCRIT and call your healthcare provider or get medical help right away.
- **Dangers of giving PROCRIT to premature babies.** PROCRIT from multi-dose vials contain benzyl alcohol. Do not give PROCRIT from multidose vials to premature babies because it can cause death and brain damage.

Common side effects of PROCRIT include:

- Rash
- Swelling in your legs and arms
- Injection site reaction, including irritation and pain

These are not all of the possible side effects of PROCRIT. Your healthcare provider can give you a more complete list. Tell your healthcare provider about any side effects that bother you or that do not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store PROCRIT?

- Store PROCRIT in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not freeze.** Do not use a vial of PROCRIT that has been frozen.
- Keep away from direct light.
- Do not shake PROCRIT.
- Throw away multidose vials of PROCRIT after 21 days from the first day that you put a needle into the vial.
- Single use vials of PROCRIT should be used only one time. Throw the vial away after use even if there is medicine left in the vial.

Keep PROCRIT and all medicines out of the reach of children.

General information about PROCRIT

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Use PROCRIT only for the condition for which it has been prescribed. Do not give PROCRIT to other people even if they have the same symptoms that you have. It may harm them.

PATIENT EDUCATION / SELF MANAGEMENT

This Medication Guide summarizes the most important information about PROCRIT. If you would like more information about PROCRIT, talk to your healthcare provider. You can ask your healthcare provider or pharmacist for information about PROCRIT that is written for healthcare professionals. For more information, go to the following website: www.PROCRIT.com or call 1-888-2ASKOBI (1-888-227-5624).

What are the ingredients in PROCRIT?

Active Ingredient: epoetin alfa

Inactive Ingredients: All formulations include albumin (human), sodium citrate, sodium chloride, and citric acid in Water for Injection. Multidose vials contain benzyl alcohol. Certain formulations also contain sodium phosphate monobasic monohydrate and sodium phosphate dibasic anhydrate.

Manufactured by:

Amgen Manufacturing, Limited, a subsidiary of Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Manufactured for:

Centocor Ortho Biotech Products, L.P.
Raritan, New Jersey 08869-0670 xxxxxxx

Printed in U. S. A.

Revised:

This Medication Guide has been approved by the U.S. Food and Drug Administration.